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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		AT	TORNEY DOCKET NO.
09/403,96	7 03/28/0	00 GUY	•	В	50019/006001
		116407000	コ	EX	AMINER
PAUL T CL	ARK	HM12/0221	•	PORTNER, V	
CLARK & ELBING				ART UNIT	PAPER NUMBER
176 FEDERAL STREET BOSTON MA 02110		• •		1645	6
				DATE MAILED:	02/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File Cope

Office Action Summary

Application No. 09/403,967

Applica...(s)

Guy et al

Examiner

Portner

Group Art Unit 1645

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X Responsive to communication(s) filed on <u>Feb 28, 2000</u>	·				
☐ This action is FINAL .					
Since this application is in condition for allowance except for formal in accordance with the practice under Ex parte Quayle, 1935 C.D. 1	1; 453 O.G. 213.				
A shortened statutory period for response to this action is set to expire is longer, from the mailing date of this communication. Failure to responsapplication to become abandoned. (35 U.S.C. § 133). Extensions of tir 37 CFR 1.136(a).	nd within the period for response will cause the				
Disposition of Claims					
Of the above, claim(s)	is/are withdrawn from consideration.				
Claim(s)					
☐ Claim(s)					
Claim(s)					
Application Papers See the attached Notice of Draftsperson's Patent Drawing Review The drawing(s) filed on is/are objected to by The proposed drawing correction, filed on is The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 Acknowledgement is made of a claim for foreign priority under 35 All Some* None of the CERTIFIED copies of the priority copies of the priority copies of the priority copies of the priority discovery in the international stage application from the International Stage application	y the Examiner. S				
Attachment(s) Notice of References Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s) Interview Summary, PTO-413 Notice of Draftsperson's Patent Drawing Review, PTO-948 Notice of Informal Patent Application, PTO-152					
SEE OFFICE ACTION ON THE FOLI	LOWING PAGES				

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DETAILED ACTION

Claims 29-58 are pending.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 29-38, drawn to compositions that comprise an immunogenic agent and a compound that promotes induction of a T-1 helper 1-type immune response.

Group II, claim(s) 39-57, drawn to a method of stimulating a T-helper 1-type immune response directed against Helicobacter.

Group III, claim(s) 58, drawn to a method of inducing a T-helper 1-type immune response against Helicobacter in a patient through administering any compound that induces a T helper 1-type immune response against Helicobacter in a patient.

2. The inventions listed as Groups I,II and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

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3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- **Group I**: 1. Saponin together with H.pylori antigen
 - 2. Cationic lipids together with H.pylori antigen;
- 3. A glycolipopeptide together with H.pylori antigen;
- 4. A combination of a saponin and a cationic lipid.
- **Group II**: 1. A method of inducing an immune response through administering a saponin together with H.pylori antigen
- 2. A method of inducing an immune response through administering a cationic lipid together with H.pylori antigen;
- 3. A method of inducing an immune response through administering a glycolipopeptide together with H.pylori antigen;
- 4. A method of inducing an immune response through administering a combination of a saponin and a cationic lipid together with H.pylori antigen.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must

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also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

Group I:Species 1: claims 29 and 32

Species 2: claims 29, 33 and 34

Species 3: claims 29, 30 and 35

Species 4: claim 31

The following claim(s) are generic: 36-38.

Group II: Species 1: claims 39 and 42

Species 2: claims 39, 43 and 44

Species 3: claims 39, 40 and 45

Species 4: claim 41

The following claim(s) are generic: 46-57.

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- 5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: structurally saponins, cationic lipids and glycolipopeptides are structurally differ and therefore do not share a common special technical feature and the prior art, W096/31235, teaches Helicobacter pylori compositions together with one of the claimed adjuvants. The claimed invention(s) are not so linked as to define a special technical that furthers the art; therefore restriction is considered proper.
- 6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
- 7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).
- 8. General Observations: The application lacks an abstract and a Brief Description of the Drawings.

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Drawings

- 9. This application has been filed with informal drawings which are acceptable for examination purposes. Attached please find PTO-948.
- 10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
30 OGY CENTER 1600